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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,364	06/08/2006	Tuen-Yee Wong	Q86490	5030

23373 7590 04/30/2008

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EXAMINER	
SNYDER, STUART	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,364	WONG ET AL.	
	Examiner	Art Unit	
	STUART W. SNYDER	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *1-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/18/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 24-42 in the reply filed on 1/18/2008 is acknowledged. The traversal is on the ground(s) that an undue search burden has not been established by the Examiner. This is not found persuasive because the standard for restriction of National Stage Applications is "lack of unity" and is independent of "undue search burden" requirements. The standard was met in the previous Office Action (11/20/2007) and not rebutted by Applicants in their response (1/18/2008).

   Claims 24-42 are examined herein; claims 1-23 are provisionally withdrawn from examination.

   The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

   The following title is suggested: "Stabilized Vaccine Compositions and Methods".

Claim Objections

3. Claim 39 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 39

recites, "The stabilized vaccine composition according to claim 24 wherein said composition which is a human or animal vaccine." Although the intended use apparently narrows the claim, in fact, neither the specification nor the claims teach how Applicants' intended use imposes structural limitations on the claimed composition. Because the intended use imposes no additional structural limitations on the claimed composition, claim 39 does not further limit claim 24.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 24-28, 30-36 and 38 is rejected under 35 U.S.C. 103(a) as obvious over Jameela, *et al*. The claims are drawn to a stabilized vaccine composition comprising immunogen coated particles having moisture content of between about 0.1 and 10% w/w. Further limitations include the immunogen comprising, *inter alia*, protein antigenic products of bacterial cells (claims 25-28), the particles are water soluble and comprises, *inter alia*, polysaccharides (claims 30-31), the composition is immunologically polyvalent (claim 32), the composition is a nucleic acid or protein (claim 33), the particle size is between 50-400 microns or 50-200 microns (claims 34-35), the composition further comprises recited stabilizers especially including buffers, salts, and adjuvants (claim 36), and the composition is immunogenic (claim 38).

Jamella, *et al*. teaches immunogenic compositions comprising chitosan microspheres coated with diphtheria toxoid (DT) and bovine serum albumin (BSA). The explicit teachings of Jamella, *et al*. encompass the limitations of claims 24-28, 30-36 and 38; diphtheria toxoid is derived from diphtheria toxin, a protein; chitosan is water soluble; buffers and salts included in the composition are phosphate buffered saline; the composition is specifically immunogenic for DT and BSA.

It is obvious to optimize result-effective variables (see MPEP 2144.05). The rejected claims recite size and moisture content limitations; each of these is independently a result-effective variable. As such, a skilled artisan at the time of the invention would have found it obvious to optimize particle size and moisture content. Said skilled artisan would have been recognized particle size (see Desai, *et al.*) and moisture content (see Precausta, *et al.*) as result-effective variables at the time of invention and therefore would have been motivated to optimize such experimental parameters in vaccine development.

Thus, the invention of claims 24-28, 30-36 and 38 is *prima facie* obvious over Jamella, *et al*. under 35 U.S.C. 103(a).

5. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jamella, *et al*. in view of Chang and Gupta. Claim 29 imposes the additional limitation on the composition that it be stable and efficacious after storage at 25º C for at least 30 days. Chang and Gupta teach a particulate vaccine composition that is stable for 30 days at 25º C (see especially, Results-Stability of Antigenic TT… section

starting in the second column of page 130). Gelatin concentration appears to be the factor most closely correlated with stability and could easily be incorporated into the composition of Jamella, *et al*. to extend the stability of their immunogenic vaccine composition.

6. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jamella, *et al*. in view of Spireas, *et al*. Claim 37 imposes the additional limitation on the composition that it be a "free flowing particulate". Spireas, *et al*. teach a compositions and methods of making such compositions comprising "free flowing particulates". The thrust of the article is the development of computational methods predicting free-flowing particulates in drug delivery. The composition of Jamella, *et al*. is used for a comparable purpose, sustained delivery of a biological. A skilled artisan would have been motivated to combine the methods to take advantage of the delivery properties of free-flowing particulates of Spireas, *et al*. and had a reasonable expectation of success given the robustness of the method and compositions of Spireas, *et al*. related to biological delivery. Thus, formulation of the composition of Jamella, *et al*. as a free-flowing particulate composition would have been *prima facie* obvious to a skilled artisan at the time of filing of the instant Application and rejection of claim 37 is proper under 35 U.S.C. 103(a).

7. Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamella, *et al*. in view of Villegas, *et al*., Macklin, *et al*. and Layton, *et al*. Additional limitations of the claims include various vertebrate pathogens

especially Newcastle Disease virus, porcine influenza, and human influenza.; Villegas, *et al*., Macklin, *et al*. and Layton, *et al*. teach particulate vaccines against such pathogens. Given the relatively limited number of approved vaccine targets, it would have been obvious at the time of the claimed invention for a skilled artisan to combine the teachings of Jamella, *et al*., Villegas, *et al*., Macklin, *et al*. and Layton, *et al*. to construct a vaccine against the named pathogens. The skilled artisan would have a reasonable expectation of success given the immunogenicity of the antigens as taught by Villegas, *et al*., Macklin, *et al*. and Layton, *et al*. and the robustness of the particles of Jamella, *et al*. in inducing an immune response.

Thus, formulation of the composition of Jamella, *et al*. combined with the antigens of Villegas, *et al*., Macklin, *et al*. and Layton, *et al*. would have been *prima facie* obvious to a skilled artisan at the time of filing of the instant Application and rejection of claims 40-42 is proper under 35 U.S.C. 103(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 24-26, 28, 30-31, 33-36, and 38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6, and 10 of U.S. Patent No. 6,974,594. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass overlapping subject matter. The limitations of the claims are a vaccine composition comprising a water soluble particle coated with an antigen; Especially viruses, bacterial or products thereof; the particles comprise, inter alia, polysaccharides and nucleic acids or polypeptides; having a particle size between 50-400 (200) microns; and wherein the particles are immunogenic in animals.

U.S. Patent No. 6,974,594 claims polysaccharide microparticles comprising antigenic biologically active material including proteins and/or microorganisms (bacteria). Thus, all of the limitations of claims 24-26, 28, 30-31, 33-36, and 38 of the instant Application are claimed in the specification of U.S. Patent No. 6,974,594.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

sws